

BMJ Open Adaptation and validation of the Distress Scale for Mexican patients with type 2 diabetes and hypertension: a cross-sectional survey

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ABSTRACT

Objectives: The aim of this study was to adapt and validate the Distress Scale for Mexican patients with type 2 diabetes and hypertension (DSDH17M).

Setting: Two family medicine clinics affiliated with the Mexican Institute of Social Security.

Participants: 722 patients with type 2 diabetes and/or hypertension (235 patients with diabetes, 233 patients with hypertension and 254 patients with both diseases).

Design: A cross-sectional survey.

Methods: The validation procedures included: (1) content validity using a group of experts, (2) construct validity from exploratory factor analysis, (3) internal consistency using Cronbach's α , (4) convergent validity between DSDH17M and anxiety and depression using the Spearman correlation coefficient, (5) discriminative validity through the Wilcoxon rank-sum test and (6) test-retest reliability using intraclass correlation coefficient.

Results: The DSDH17M has 17 items and three factors explaining 67% of the total variance. Cronbach α ranged from 0.83 to 0.91 among factors. The first factor of 'Regime-related Distress and Emotional Burden' moderately correlated with anxiety and depression scores. Discriminative validity revealed that patients with obesity, those with stressful events and those who did not adhere to pharmacological treatment had significantly higher distress scores in all DSDH17M domains. Test-retest intraclass correlation coefficient for DSDH17M ranged from 0.92 to 0.97 among factors.

Conclusions: DSDH17M is a valid and reliable tool to identify distress of patients with type 2 diabetes and hypertension.

INTRODUCTION

Distress is a non-psychiatric emotional burden in patients with chronic diseases.^{1 2} Emotional distress is non-specific to a chronic disease as observed in patients with diabetes, hypertension, cancer, multiple

Strengths and limitations of this study

- We adapted and validated the Diabetes Distress Scale (DDS17) for patients with type 2 diabetes and hypertension, considering that both are frequent chronic diseases often occurring together that have common risk factors, severe long-term complications and require several common self-care strategies—circumstances that can cause distress.
- The study provides the evidence that the Distress Scale for Mexican patients with type 2 diabetes and hypertension (DSDH17M) is valid and reliable and describes specific problems that contribute to distress patients in these populations.
- The primary limitation of this study is that the DSDH17M validation was performed only in a group of patients treated at two family medicine clinics of Instituto Mexicano del Seguro Social (IMSS) in Mexico City, possibly limiting generalisability of the results.

sclerosis and HIV, among others.² Its prevalence among patients with chronic disease varies according to disease type, severity, treatment, availability of psychological support by healthcare providers, family and community.²⁻⁶ Emotional distress may occur in response to the disease manifestation, progression, complications, impact on self-concept and need of continuous non-pharmacological and pharmacological treatment, among others.²⁻⁵ Timely detection and management of emotional distress in patients with chronic disease is associated with better self-care, quality of life and health outcomes.⁷ Emotional distress needs to be differentiated from depression due to the differences in underlying treatment.

Diabetes and hypertension are two of the most common chronic diseases worldwide. Furthermore, the prevalence of hypertension in persons with diabetes varies between 50%

and 90%.⁸ Up to 75% of patients with diabetes die from cardiovascular disease attributed to hypertension.⁹ Yet, most research on emotional distress focuses primarily on diabetes with little concern regarding to hypertension or their co-occurrence. Several Diabetes Distress Scales (DDS) have been validated, whereas according to our knowledge the General Health Questionnaire (12GHQ) is the only scale that has been used for measuring hypertension-related distress.⁵ Furthermore, 12GHQ and several specific distress scales (eg, Problem Areas in Diabetes (PAID) scale) lack some dimensions of the construct (eg, patients' feelings about their healthcare provider) that are relevant for patients with chronic diseases.¹⁰ To overcome these problems, the DDS17 was developed with the aim of measuring patients distress levels in response to the emotional burden, care regimen, interpersonal factors and physician care.¹⁰ However, this scale focuses only on patients with diabetes.

Type 2 diabetes and hypertension are frequently coexistent chronic diseases with common socially determined lifestyle risk factors (eg, stress, sedentary lifestyle, unhealthy food). When poorly controlled, both diseases can cause severe long-term complications. Their control requires adherence to common self-care strategies (eg, diet, physical exercise and pharmacological treatment) and continuous monitoring (eg, visits to the healthcare professionals, laboratory tests, self-monitoring of blood pressure and blood sugar). All the factors mentioned above can provoke distress. The recognition of these common circumstances of chronic diseases has led healthcare researchers to the development of an Integrated Chronic Care Model that focus on integrative healthcare of chronic patients.¹¹ Also, the magnitude of chronic diseases has prompted to build a measurement framework for the burden of treatment in patients with chronic conditions.¹² All these efforts acknowledge that today patients have frequent multiple chronic comorbidity that requires general tasks of treatment and self-care.

In Mexico, the prevalence of type 2 diabetes and hypertension in adults is high. The prevalence of diabetes increased from 7% in 2006 to 9.2% in 2012, whereas the prevalence of hypertension has remained at 31.5%.¹³ Mexican studies on emotional disorders among diabetic and hypertensive patients focus primarily on depression and have reported a high prevalence (24–48%).^{14–16} Although it is recognised that emotional distress is frequent in patients with diabetes and hypertension, little is known about the magnitude of this problem in Mexico; hence, its study and clinical treatment are likely to be deficient. One of the reasons for the paucity of research on emotional distress in patients with diabetes and hypertension in Mexico is the lack of a rigorously validated instrument for assessment of this condition. To our knowledge, an attempt was made to validate the PAID scale.^{17–18} However, this Mexican adoption of PAID only has partial validation that includes construct validity through exploratory factor analysis, internal consistency with Cronbach's α

and convergent validity analysis and lacks the content validity; furthermore, it has the same deficiencies regarding the dimensions of the PAID construct as the original scale.^{17–18}

To close these gaps in the literature, the objective of this study was to adapt and validate a Mexican version of the distress scale for patients with type 2 diabetes and hypertension.

METHODS

In 2014, we conducted a cross-sectional survey in two family medicine clinics affiliated with the Mexican Institute of Social Security (IMSS). The IMSS extends coverage to 48.8% of the Mexican population, providing healthcare for employees in the formal labour sector and their families.¹⁹ Clinics were selected according to convenience from the list of IMSS Mexico City ambulatory clinics: one from the northern area and the other from the southern area of the city. The clinics had the same services and infrastructure.

Participants

The inclusion criteria considered patients 20 years of age or older, with type 2 diabetes, hypertension or both and with at least 3 months since their diagnosis. We focused on patients with type 2 diabetes, as at IMSS patients with type 1 diabetes usually attend follow-up visits with specialist at the secondary care hospital settings, while patients with type 2 diabetes (that accounts for more than 90% of all diagnosed diabetes cases at IMSS) receive care from family doctors at the family medicine clinics.

Two nurses received a 1-week training course to supervise the fieldwork including participant identification and recruitment and questionnaire application. Nurses interviewed all available patients with type 2 diabetes and/or hypertension in the morning and evening shifts. Patients fulfilled the inclusion criteria and agreed to participate in the study after signing informed consent. Nurses also verified the patients' height, weight, diagnoses and treatment in the electronic health records.

Study variables

The primary study variable was emotional distress. We adopted the DDS17¹⁰ for patients with diabetes and hypertension and validated it in the sample of Mexican patients. The original DDS is a 17-item scale with four domains: distress associated with emotional burden, care regimen, interpersonal factors and physician care.¹⁰ Each item is rated on a 6-point scale ranging from 'not a problem' to 'a very serious problem'. The mean score was obtained for each domain as the sum of the items in each domain divided by the number of items in the domain.

To describe the characteristics of the study population and validate the distress scale for patients with diabetes and hypertension (DSDH17M), we collected information

regarding patient's age; sex; education and marital, employment and nutritional status. Nutritional status was classified into four groups according to body mass index (BMI): low weight (BMI < 18.5 kg/m²), normal weight (BMI 18.5–24.9 kg/m²), overweight (BMI 25.0–29.9 kg/m²) and obese (BMI ≥ 30.0 kg/m²). A stressful event was considered if the response was affirmative to the question of whether he/she had at least one negative stressful event during the previous month. To facilitate the answer to this question we provided a list of 28 stressful events selected from the scale of Holmes and Rahe.²⁰ Also, at the end of this list, the patient was asked if he/she had any other negative stressful event during the previous month.

We included information on the clinical history such as duration of diabetes and/or hypertension after diagnosis and presence of any diabetes and/or hypertension-related complications. The Hospital Anxiety and Depression Scale (HADS) assessed depression (seven items) and anxiety (seven items)²¹ using a 4-point Likert response format with each subscale ranging from 0 to 21. Scores ≥ 11 identify the possible presence of anxiety or depression. Adherence to pharmacological treatment was ascertained when a patient reported complying with the indicated doses and schedules for all prescribed medications during the prior month. Blood pressure control was defined when, during the medical visit, blood pressure was < 130/80 mm Hg for patients with comorbidity of diabetes and hypertension and < 140/90 mm Hg for those who only had hypertension.²² Glucose control was defined when the patient had glycated haemoglobin (HbA1C) < 7 or in the absence of this test when their fasting plasma glucose was < 130 mg/dL in the last measurement.²³

Procedures

The sample size was based on the practice of ensuring a person-to-item ratio of 10:1.²⁴ It also considered 20% of losses during the survey (< 80% of the information obtained). Therefore, minimum sample size calculated was 221 patients for each diagnosis (diabetes, hypertension or both). Patients from two clinics were included to obtain the necessary sample size and greater generalisability of the study results.

Validation of the DSDH17M was performed in two stages as follows:

Stage 1: DDS17 was translated into (Mexican) Spanish by a bilingual translator and then translated back to English (back translation) by another bilingual translator. Adoption of the scale for both populations (patients with diabetes and/or hypertension) was achieved by including the phrase 'diabetes and/or hypertension' in each item. Then, a group of experts evaluated the content validity of the scale for both diseases. This group included two health systems researchers specialised in family medicine, one psychologist, one medical sociologist and one nurse. All members of the group had experience in the care of patients with diabetes and hypertension and validation of health assessment tools.

All members were invited to assess the appropriateness of the language and whether each item of the adapted DSDH17M was representative of the concept that the instrument purports to measure. Finally, experts rated each item as 1='not relevant', 2='useful but not relevant' or 3='relevant'. Expert responses were grouped and those who rated the items as 'relevant' were counted. Content validity index (CVI) for each item was calculated as $(ne - N/2) / (N/2)$, where 'ne' was the number of experts who indicated the item as 'relevant' and 'N' was the total number of experts.²⁵ Content analysis showed that all DDS17 items can be applied for both diseases since all the items are formulated in general terms and avoid treatment and self-care particularities. There were no indications that items needed to be replaced or eliminated as all items obtained a CVI > 0.7. Also, a pilot pretest of the scale in 25 patients was performed to assure clarity of items from a linguistic and cultural view. Online supplementary appendix 1 presents the adopted DSDH17M questionnaire.

Stage 2: Descriptive analysis served to depict participant's characteristics, calculate mean, SD, skewness, kurtosis and frequency of distribution of each item of the adopted DSDH17M questionnaire. Corrected item-total correlations were computed to determine if the behaviour of each item was consistent with the other items in the same factor of the original scale.²⁶ Exploratory factor analysis was carried out based on the polychoric correlation matrix of the whole sample. Three and four factors were extracted using generalised least squares. In all cases, the solution was analysed without being rotated and after varimax, and oblimin rotations were applied.²⁷ Factor loadings > 0.4 were considered significant.²⁸ Percentage of variance explained by each factor and communality of each item were computed.

We also performed separate factor analysis for patients with diabetes and hypertension and for those patients with both diseases, and carried out a multiple group confirmatory factor analysis²⁹ to test whether the three groups of patients differed with regard to the underlying constructs. When successive invariance models (configural, weak, strong and strict) were compared, the incremental comparative fit index was < 0.01, that is, the measurement model is invariant across the studied populations. Therefore, we present only the analyses for the whole sample of patients.

Cronbach's α and the average interitem correlation were used to measure the internal consistency of items associated with the same factor; α coefficients around 0.80 were considered acceptable.²⁶ A score for each factor was calculated by summing all item responses within each factor and dividing by the total number of factor items. Convergent validity between the score factors and other measures of psychosocial well-being— anxiety and depression—were assessed by calculating Spearman's rank correlation coefficient; $r < 0.35$ was considered to represent weak correlations, r ranging from 0.36 to 0.67 represent moderate correlations and from

0.68 to 1.0 high correlations.³⁰ Wilcoxon rank-sum test served to evaluate the ability of the score factors to discriminate between subpopulations defined by different clinical and personal characteristics of the participants. We hypothesised that females with less education, those who reported stressful events and emotional problems, had obesity and complications of diabetes and/or hypertension, disease duration <3 years, did not adhere to treatment and did not have blood pressure and glucose control may present higher distress in all domains.^{4-6 31}

Test-retest reliability was assessed by applying the DSDH17M twice with a lag time of 5 days to a subgroup of 35 participants. For each participant, two global mean scores and two mean scores for each factor were calculated and compared using the intraclass correlation coefficient (ICC); ICC >0.75 was considered excellent, 0.40–0.75 fair to good and <0.40 poor.³² All analyses were performed with R Core Team 2015 V.3.1.3 and STATAV.12.

RESULTS

Of 856 eligible patients, 722 (84.3%) agreed to participate. Reasons for not accepting to participate were the lack of time (61.9%), no interest in responding to the survey (27.6%) and fatigue or feeling poorly (10.5%).

Table 1 describes the general characteristics, nutritional status, medical history, adherence to pharmacological treatment and disease control of study participants. The study included 722 patients, the majority being female (73%). Mean age was 58.2±10.4 years. Almost half (47%) completed only elementary school or less and were not employed. Most participants lived with a life partner. A total of 0.3% had a low weight, 16.0% had a normal weight, 36.1 were overweight and 47.6% had obesity; 32.5% had diabetes, 32.3% had hypertension and 35.2% had both diseases. Median time elapsed since diagnosis was 8 years; 61.5% had diabetes and/or hypertension complications, 12.3% reported some stressful event in the last month, 22% had anxiety and 9% had depression according to the HAD scale, whereas 54.8% attained good treatment adherence, 54.4% had blood pressure control and 46% of patients with diabetes had glucose control. Furthermore, online supplementary appendix 2 describes patients' characteristics according to the disease group (diabetes, hypertension and both diseases).

Table 2 presents summary statistics of the DSDH17M. 'Not a problem' was the most frequent response for all items of the questionnaire. The three items in which most participants responded not having a problem were feeling that 'the physician does not have sufficient knowledge about diabetes and/or hypertension', 'friends or family do not provide emotional support' and 'friends or family do not appreciate how difficult living with diabetes and/or hypertension can be'. The three items with the highest percentages of responses of having somewhat serious, serious or very serious problems were feeling that 'he/she will end up with serious

Table 1 General characteristics, nutritional status, medical history, adherence to treatment and disease control (n=722)

	Per cent
<i>General characteristics</i>	
Sex	
Male	27.0
Female	73.0
Age, years, mean (SD)	58.18 (10.4)
Age groups	
<65	71.2
≥65	28.8
Schooling	
Elementary school or less	47.0
Secondary school or higher	53.0
Occupation	
Retired or pensioner	22.6
Remunerated job	30.3
Not employed	47.1
Married or with life partner	64.4
<i>Nutritional status</i>	
Low weight	0.3
Normal weight	16.0
Overweight	36.1
Obese	47.6
<i>Medical history</i>	
Type 2 diabetes	32.5
Hypertension	32.3
Diabetes and hypertension	35.2
Duration of diabetes and/or hypertension, years, mean (SD)	8.7 (6.2)
Complications of diabetes and/or hypertension	61.5
Presence of stressful events in the last month	12.3
Anxiety	22.0
Depression	9.0
Number of medications	
1–2	23.5
3–4	36.5
≥5	40.0
Insulin therapy in patients with diabetes	n=489 25.4
<i>Adherence and disease control</i>	
n=722	
Adherence to pharmacological treatment	54.8
Blood pressure control	54.4
Glucose control	n=489 46.0

long-term complications regardless of what they do' (28.7%), 'diabetes and/or hypertension are consuming too much of their mental and physical energy' (28.6%) and 'he/she is not closely adhering to a good meal plan' (28.3%).

Corrected item-total correlations were >0.47, therefore the response to any given item was consistent with those of other items in the same dimension as in the original DDS17. SDs were >1, thus an adequate variability among responses was observed. Nevertheless, means ranged from 1.5 to 3 so the distribution of the answers had a

Table 2 Descriptive statistics and item-total correlations of DSDH17M (n=722)

Items	Not a problem Per cent	Slight problem Per cent	Moderate problem Per cent	Somewhat serious problem Per cent	Serious problem Per cent	Very serious problem Per cent	M (SD)	Skewness	Kurtosis	Corrected item-total correlation
<i>Emotional burden</i>										
Feeling overwhelmed by the demands of living with diabetes and/or hypertension	40.7	17.6	19.3	7.2	11.1	4.2	2.43 (1.54)	0.79	-0.55	0.77
Feeling angry, scared and/or depressed when I think about living with diabetes and/or hypertension	43.5	13.3	16.5	8.4	12.0	6.2	2.51 (1.66)	0.72	-0.83	0.73
Feeling that diabetes and/or hypertension control my life	52.9	11.5	13.0	6.9	10.4	5.3	2.26 (1.63)	0.98	-0.42	0.68
Feeling that diabetes and/or hypertension are taking up too much of my mental and physical energy everyday	31.0	17.3	23.0	9.3	12.7	6.6	2.75 (1.60)	0.53	-0.88	0.62
Feeling that I will end up with serious long-term complications, no matter what I do	31.7	18.8	20.8	7.9	13.9	6.9	2.74 (1.63)	0.56	-0.92	0.61
<i>Regimen-related distress</i>										
Not feeling confident in my day-to-day ability to manage diabetes and/or hypertension	64.4	11.2	10.2	4.6	7.1	2.5	1.86 (1.40)	1.52	1.13	0.73
Not feeling motivated to keep up my diabetes and/or hypertension self-management	58.2	12.2	13.3	5.7	7.5	3.2	2.02 (1.46)	1.28	0.44	0.69
Feeling that I am often failing with my diabetes and/or hypertension routine	45.2	22.6	16.2	5.4	7.9	2.8	2.17 (1.40)	1.12	0.28	0.69
Feeling that I am not sticking closely enough to a good meal plan	35.5	17.9	18.4	9.4	13.6	5.3	2.64 (1.61)	0.59	-0.91	0.60
Feeling that I am not testing my blood sugars and/or blood pressure frequently enough	60.5	10.7	12.5	4.8	8.0	3.5	2.00 (1.48)	1.32	0.49	0.54
<i>Interpersonal distress</i>										
Feeling that friends or family do not appreciate how difficult living with diabetes and/or hypertension can be	72.3	8.6	6.5	3.2	6.4	3.0	1.72 (1.38)	1.87	2.22	0.86
Feeling that friends or family do not give me the emotional support that I would like	75.1	6.1	6.0	3.9	5.5	3.5	1.69 (1.39)	1.92	2.40	0.80
Feeling that friends or family are not supportive enough of self-care efforts (eg, planning activities that conflict with my schedule, encouraging me to eat the 'wrong' foods)	71.6	8.9	7.6	2.8	6.2	2.9	1.72 (1.36)	1.87	2.28	0.78
<i>Physician-related distress</i>										
Feeling that my doctor does not take my concerns seriously enough.	59.1	7.2	8.6	5.0	10.2	9.8	2.30 (1.81)	1.01	-0.59	0.77

Continued



Table 2 Continued

Items	Not a problem Per cent	Slight problem Per cent	Somewhat serious problem		Very serious problem		M (SD)	Skewness	Kurtosis	Corrected item-total correlation
			Per cent	Per cent	Per cent	Per cent				
Feeling that my doctor does not give me clear enough directions on how to manage my diabetes and/or hypertension	53.3	10.9	10.7	5.1	10.7	9.3	2.37 (1.78)	0.94	-0.64	0.76
Feeling that my doctor does not know enough about diabetes and/or hypertension	77.6	6.0	5.3	3.2	5.1	2.9	1.61 (1.32)	2.13	3.29	0.59
Feeling that I do not have a doctor who I can see regularly enough about my diabetes and/or hypertension	65.1	6.1	8.9	4.0	11.1	4.8	2.04 (1.64)	1.26	0.04	0.54

DSDH17M, Distress Scale for Mexican patients with type 2 diabetes and hypertension; M, mean.

positive skew for every item. Most responses were in the lower end of the Likert response format; specifically, more than 70% of the patients chose one of the following responses: 1=not a problem, 2=a slight problem or 3=a moderate problem.

Online supplementary appendix 3 provides information on descriptive statistics and item-total correlations of DSDH17M according to the disease group (diabetes, hypertension and both diseases).

Table 3 presents the three-factor model with a varimax rotation. This model was similar to the three-factor model with an oblimin rotation. The four-factor models (with a varimax rotation and with an oblimin rotation) did not produce a loading matrix with a simple structure and a Heywood case was reported in one case. The model in table 3 explained 67% of the total variance. Ten items were associated with factor 1 labelled as 'regimen-related distress and emotional burden'. This factor explained 33% of variance. Items associated with factor 1 had communality values between 0.37 and 0.78. Three items defined factor 2 referred to as 'interpersonal distress'. This factor explained 16% of the total variance and had communalities between 0.80 and 0.93. Finally, four items were related to factor 3 called 'physician-related distress'. Factor 3 explained 18% of the total variance and communalities ranged from 0.51 to 0.88.

Table 4 presents the results of reliability and convergent validity analysis. The average interitem correlation was >0.5 for the three factors. Internal consistency as measured by Cronbach α was 0.91 for factors 1 and 2 with 95% CIs (95% CI 0.89 to 0.93) and (95% CI 0.85 to 0.96), respectively. Cronbach α for factor 3 was 0.83 (95% CI 0.78 to 0.88). For the whole set of items, Cronbach α was 0.91 (95% CI 0.89 to 0.92) and the average interitem correlation was 0.37.

The scores of the three domains of the DSDH17M had a positive and significant correlation with the anxiety and depression HADS subscales. Factor 1 of the DSDH17M was moderately correlated with anxiety ($r=0.533$, $p<0.0001$) and depression subscales ($r=0.525$, $p<0.0001$) of HADS, whereas the other two factors had a weak correlation with anxiety and depression subscales.

Discriminative validity analysis is summarised in table 5. Wilcoxon rank-sum test indicated that women, patients with obesity and those with stressful events and non-adherence to pharmacological treatment had significantly higher distress scores in all DSDH17M domains.

The test-retest ICCs were 0.92 for physician-related distress, 0.96 for regimen-related distress and emotional burden, 0.97 for interpersonal distress, and for the average of all items.

DISCUSSION

This study has two important contributions to the analysis of patients with chronic distress. It adapts DDS17 for patients with diabetes and/or hypertension and provides the evidence that the Distress Scale for Mexican

Table 3 Factor analysis of DSDH17M (n=722)

Items	Factor loadings			Communality values
	F1 Regimen-related distress and emotional burden	F2 Interpersonal distress	F3 Physician-related distress	
Feeling overwhelmed by the demands of living with diabetes and/or hypertension	0.85	0.09	0.12	0.75
Not feeling confident in my day-to-day ability to manage diabetes and/or hypertension	0.84	0.23	0.17	0.78
Feeling angry, scared and/or depressed when I think about living with diabetes and/or hypertension	0.80	0.16	0.20	0.71
Not feeling motivated to keep up my diabetes and/or hypertension self-management	0.81	0.20	0.19	0.74
Feeling that diabetes and/or hypertension control my life	0.75	0.17	0.11	0.60
Feeling that diabetes and/or hypertension are taking up too much of my mental and physical energy every day	0.70	0.06	0.08	0.49
Feeling that I am often failing with my diabetes and/or hypertension routine	0.72	0.26	0.17	0.61
Feeling that I will end up with serious long-term complications, no matter what I do	0.68	0.20	0.09	0.51
Feeling that I am not testing my blood sugars and blood pressure frequently enough	0.52	0.22	0.24	0.37
Feeling that I am not sticking closely enough to a good meal plan	0.56	0.34	0.14	0.44
Feeling that friends or family do not appreciate how difficult living with diabetes and/or hypertension can be	0.27	0.88	0.28	0.93
Feeling that friends or family are not supportive enough of self-care efforts (eg, planning activities that conflict with my schedule, encouraging me to eat the 'wrong' foods)	0.25	0.80	0.30	0.80
Feeling that friends or family do not give me the emotional support that I would like	0.30	0.82	0.30	0.86
Feeling that my doctor does not give me clear enough directions on how to manage my diabetes and/or hypertension	0.06	0.20	0.91	0.88
Feeling that my doctor does not take my concerns seriously enough	0.15	0.18	0.91	0.88
Feeling that my doctor does not know enough about diabetes and/or hypertension and also about diabetes and/or hypertension care	0.24	0.20	0.72	0.61
Feeling that I do not have a doctor who I can see regularly enough about my diabetes and/or hypertension	0.23	0.26	0.62	0.51
Per cent of the variance	33	16	18	Total variance 67

Bold values highlight the factor loadings >0.4.

DSDH17M, Distress Scale for Mexican patients with type 2 diabetes and hypertension.

patients with type 2 diabetes and hypertension (DSDH17M) is valid and reliable.

Adaptation of psychological instruments is a complex process requiring evidence of the semantic equivalence of the items, cultural fit of the instrument and adequate psychometric properties.³³ The original DDS17 is a well-

known scale for measuring levels of diabetes distress and areas of concern that cause the distress.¹⁰ This scale was developed in English¹⁰ and later translated, adapted and validated in several cultures, including Danish,³⁴ Norwegian,³⁵ Chinese³⁶ and Chilean.³⁷ The adaptation of a DDS17 for diabetes and hypertension is justified by

Table 4 Reliability and convergent validity of DHDS17M (n=722)

	F1 Regimen-related distress and emotional burden	F2 Interpersonal distress	F3 Physician-related distress
Average interitem correlation	0.51	0.77	0.55
Cronbach's α (95% CI)	0.91 (0.89 to 0.93)	0.91 (0.85 to 0.96)	0.83 (0.78 to 0.88)
Correlation among DSDH17M domains and HADS			
Anxiety	0.533*	0.298*	0.268*
Depression	0.525*	0.339*	0.225*

Convergent validity between DSDH17M and anxiety and depression scales by calculating Spearman's rank correlation coefficient.

*Correlation is significant at the 0.0001 level.

DSDH17M, Distress Scale for Mexican patients with type 2 diabetes and hypertension; HADS, Hospital Anxiety and Depression Scale.

the frequent coexistence of both diseases, by the presence of general tasks of treatment and self-care that these diseases share and that can cause distress. Also, content validity of the DDS17 scale was achieved by the

confirmation of the relevance of all the items of the DDS17 for both diseases by the group of experts.

During the content analysis of the DSDH17M, a concern was raised about the difficulties in interpreting

Table 5 Discriminative validity of DSDH17M through analysis of Wilcoxon rank-sum test (n=722)

Variable	Categories	F1 Regimen-related distress and emotional burden	F2 Interpersonal distress	F3 Physician-related distress
Mean (SD)		2.33 (1.15)	1.71 (1.26)	2.08 (1.34)
Median		2.0	1.0	1.5
		Median	Median	Median
Sex	Female	2.1	1.0	1.5
	Male	1.8	1.0	1.3
Schooling	Elementary school or less	2.0	1.0	1.5
	Secondary school or higher	2.0	1.0	1.5
Obesity	Yes	2.1	1.0	1.5
	No	1.9	1.0	1.3
Stressful events	Yes	3.0	1.7	2.5
	No	1.9	1.0	1.3
Duration of diabetes and/or hypertension	≤3 year	1.9	1.0	1.6
	>3 year	2.0	1.0	1.5
Complications of diabetes or hypertension	Yes	2.0	1.0	1.5
	No	2.0	1.0	1.3
Adherence to pharmacological treatment	Yes	1.8	1.0	1.3
	No	2.4	1.0	1.8
Blood pressure control	Yes	2.0	1.0	1.3
	No	2.1	1.0	1.5
Glucose control	Yes	1.9	1.0	1.3
	No	2.1	1.0	1.5
Wilcoxon rank-sum		p Value	p Value	p Value
Sex		0.002	0.005	0.013
Schooling		0.840	0.489	0.596
Obesity		0.004	0.011	0.033
Stressful events		<0.0001	<0.0001	<0.0001
Duration of diabetes and/or hypertension		0.299	0.652	0.321
Complications of diabetes or hypertension		0.913	0.494	0.170
Adherence to pharmacological treatment		<0.0001	0.005	0.008
Blood pressure control		0.146	0.793	0.175
Glucose control		0.058	0.794	0.200

DSDH17M, Distress Scale for Mexican patients with type 2 diabetes and hypertension.

the results when both diseases co-occur. The conclusion was that in this case, the scale allows evaluating the level of distress and the area(s) of greater distress for both conditions and can be interpreted as the impact/burden of comorbidity on the patient. Because one cannot be sure that some dimensions of the distress caused by one chronic disease do not overlap with dimensions of the distress that other chronic disease causes in the same patient, if measured with two scales that measure very similar domains of what causes the diseases distress. In fact, one could expect to find a joint effect that not even the patient can separate.

The DSDH17M adapted for Mexican patients with diabetes and/or hypertension has acceptable psychometric characteristics. Consistent with the original DDS17, the DSDH17M preserved 17 items. This is different from the results of the DDS validation in China³⁶ and Chile³⁷ where researchers eliminated several items (two and four, respectively). The factorial structure of DSDH17M has three factors. The first factor combined distress related to the treatment regimen and emotional burden, whereas the other two factors (interpersonal and physician-related distress) remained separate. This factor structure is different from the original scale that has four factors but is similar to the DDS validated in China (CDDS).³⁶ The DSDH17M explained 67% of the total variance that was greater, comparing with the Chinese version (62.4%).

Internal consistency of the DSDH17M was acceptable with Cronbach's α values ranging from 0.83 to 0.91, similar to the original, Danish, Norwegian and Chinese scales and different from the results of the DDS validation in Chile,³⁷ where Cronbach's α ranged from 0.62 to 0.75. DSDH17M also has test-retest reliability higher than the Chinese version (0.97 vs 0.74).³⁶ Regarding the convergent validity, the factor 'regimen-related distress and emotional burden' of DSDH17M was moderately correlated with anxiety and depression found during validation of Chinese and Norwegian versions of the DDS.

Discriminative validity analyses of the DSDH17M revealed higher distress for females, patients with obesity, those with stressful events and non-adherence to pharmacological treatment. Chinese researchers also found a correlation of DDS with obesity and quality of life. Contrary to results from other studies, DSDH17M score did not differ significantly according to the complications of diabetes³⁵ or hypertension, glucose^{1 34-37} or blood pressure control.

Multiple group confirmatory factor analysis indicated that the measurement model is invariant across studied populations. This finding is congruent with previous research identifying the presence of distress in patients with diabetes or hypertension. It also highlights the common problems related to distress in these patients. Congruent with the findings in Danish patients with type 1 diabetes, we found that for Mexican patients with diabetes 2 and/or hypertension the least frequent concerns were those related to physician-related

distress. A high percentage of patients in both cultures reported that there was no problem regarding 'the physician does not have sufficient information about diabetes and/or hypertension'. The items in which most participants responded having serious problems were from the domain of regimen-related distress and emotional burdens: 'feeling that they will end up with serious long-term complications regardless of what they do' and that 'diabetes and/or hypertension are consuming too much of their mental and physical energy' were major concerns followed by 'feeling that they are not closely adhering to a good meal plan'. These problems were similar to those reported by the Danish study. These findings highlight the need for comprehensive team-based care as proposed by the Chronic Care Model where the physician, nurse, psychologist, nutritionist and other health providers work collaboratively to meet the needs of patients with chronic illnesses and build their practical skills and confidence in self-care and improve health outcomes.^{11 38}

The primary limitation of this study is that the DSDH17M validation was performed only in a group of patients treated at two family medicine clinics of IMSS in Mexico City, possibly limiting generalisability of the results. Therefore, we recognise the need to validate DSDH17M in other settings in Mexico to corroborate the factor structure of this scale. Furthermore, the DSDH17M was validated only in a sample of patients with hypertension and type 2 diabetes; however, the original DDS17 was validated for patients with type 2 and type 1 diabetes. Thus, further validation of this scale in patients with type 1 diabetes in the Mexican context is advisable. Additionally, it would be worth to assess whether the instrument has sensitivity for detecting changes in distress over time.

In conclusion, DSDH17M is a valid and reliable tool to identify distress in patients with type 2 diabetes and/or hypertension and describe specific problems that contribute to patients with distress in these populations.

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